

Subject: Whistleblower letter
From: Brad Racino <bradracino@inewsource.org>
Date: 8/12/19, 12:48 PM
To: kkantelo@ucsd.edu
CC: Jill Castellano <jillcastellano@inewsource.org>

Good afternoon Mr. Kantelo,

This morning we received a whistleblower complaint alleging a number of problems within UCSD's HRPP (attached).

The letter specifically referred to actions taken by you in regards to your leadership position within UCSD.

Please find the following list of questions and let me know when would be a good time to talk about them:

1. How do you plan to address the concerns raised in this letter? Will you conduct an investigation into the claims?
2. The letter says that under your leadership, IRB committees have been pressured to approve studies that do not meet the criteria for approval, adding that senior leadership at HRPP "purposefully neglects" or "perpetuates" noncompliance. Are these statements accurate? Have you been ensuring that research studies performed at UCSD meet all government regulations and UCSD policies before approving them?
3. The letter also says higher-ups have shopped protocols to different IRB committees or commercial IRBs to obtain approval. Have you encouraged any researchers with risky studies that may have been denied or deferred by a UCSD IRB committee to submit their study applications to commercial IRBs instead?
4. The letter says that unlike other HRPP offices in the UC system that are housed under the Vice Chancellor for Research Compliance, the UCSD HRPP is overseen by the ACTRI Director. Do you believe this creates a conflict of interest when HRPP is expected to independently review research? Have any efforts been made to move the office out from under the ACTRI Director?
5. Does the HRPP promptly report unanticipated problems, serious or continuing noncompliance and suspension/termination of IRB approval to institutional officials or the FDA?
6. The letter claims that often IRB members don't have the expertise necessary to make determinations required for research approval. Is that true? Is HRPP making any attempts to look for people with more expertise?
7. Is it true that the IRBs do not review researchers' conflict of interest plans? How does the university ensure that researchers don't have conflicts of interest that could interfere with their research? How does the university ensure that research participants are aware of any conflicts if UCSD is not reviewing these conflict of interest policies?
8. Does the HRPP have anything like the Quality Improvement Unit (QIU) at UCSF or UCLA to review staffing levels and conduct post-approval monitoring, education/training

and other quality improvement activities? If not, would UCSD consider establishing a unit like this to ensure its IRBs are following their mission and protecting research subjects?

9. The letter references a PowerPoint presentation with two slides about enshrining and incentivizing flexibility and “To be defined: policymaking process, appeals process.” Can you please tell me if those slides were indeed presented, and if so, what you meant by each?

10. The letter alleges “corporate partners” – meaning investors – are paraded through the HRPP work spaces. Is this true? If so, what is the reason for doing that?

11. The letter says the HRPP staff has not received performance evaluations and that, as a result, you have been sent “noncompliant” emails. Are either of these statements true? If so, please explain.

Thank you for your time.

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— Attachments: —

Noncompliance and Human Subject Research Violations Report at
UCSD.pdf

129
KB